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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,775	10/07/2005	Masayoshi Yamaguchi	4532660/55140	5188

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EXAMINER	
HENLEY III, RAYMOND J	
ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
11/26/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/532,775	YAMAGUCHI, MASAYOSHI	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 19-27 ARE PRESENTED FOR EXAMINATION

Applicant's Pre-Appeal Brief Request for Review filed August 17, 2010 has been received and entered into the application.

Upon consideration of Applicant's remarks and the rejections of record, the previous Office action dated May 17, 2010 is vacated and thus, all rejections set forth therein are withdrawn.

A new rejection of the claims will follow because it is agreed that beta-carotene is not the exact same molecule as beta-cryptoxanthin, which cryptoxanthin is the subject of the present claims.

Claim Rejection - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shlyankevich, (U.S. Patent No. 5,424,331; previously cited by the Examiner).

Shlyankevich teaches a method for treating osteoporosis, (a.k.a. a disease of decreased osteogenesis), which comprises administering to a patient in need thereof an effective amount of beta-carotene, (a.k.a. a pro-vitamin A compound) which may be in an amounts of 6 mg or 20 mg, (see the abstract, col. 4, lines 24-31 and Examples 1 and 3). Further, the patentee teaches this method for postmenopausal women, especially those who are at least 50-55 years of age, (col. 5, lines 26-31; a.k.a., bone loss associated with aging vs. present claim 1).

While the patentee fails to teach "purified" beta-carotene or beta- cryptoxanthin, there would have been only two choices for the skilled artisan, i.e., purified or un-purified, and thus it is deemed that the element of claim 1 for purified beta-carotene is an element that would have been immediately envisaged by one skilled in the art.

The difference between the above and the claimed subject matter lies in that the patentees fails to teach (a) beta-cryptoxanthin, (a.k.a., a vitamin A product), as in the present claims; and (b) an amount ranging between about 100 and about 1000 μg per kilogram of body weight.

However, the difference between the subject matter sought to be patented and the prior art is such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because (a) the patentees provide for a wide dosage regimen for the vitamin A product, i.e., "5 to 20 parts" per composition, (see, e.g., col. 3, line 27); and (b) as acknowledged by Applicant at page 3 of the present specification, the claimed beta-cryptoxanthin was known to have characteristic properties of provitamin A while the beta-carotene of the prior art was well known to be a pro-vitamin A compound. Nothing inventive is seen in selecting one or more compounds where each compound was known to have the same characteristic properties.

"Generally, differences in concentration or temperature will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" (see MPEP 2144.05(II)).

The determination of the optimum dosage regimen to employ with the presently claimed active agents would have been a matter well within the purview of one of ordinary skill in the art and such determination would have been made in accordance with a variety of factors. These would have included the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and whether the compound is administered a part of a drug combination. Thus, the dosage regimen that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent the dosages that would have been determined by the skilled artisan.

Secondly, as noted above and as acknowledged by Applicant at page 3 of the present specification, beta-cryptoxanthin of the present claims was well known to have characteristic properties of provitamin A while it was well known that "provitamin A" was also known as beta-carotene, albeit less potent, (see the present specification at page 3, lines 15-18. Thus, it would have been obvious to use the presently claimed beta-cryptoxanthin instead of the beta-carotene of the prior art due to the similarity in characteristics.

The Examiner is aware of no legal authority which dictates that one similar compound must be exactly the same in degree of efficacy as another compound before one skilled in the art would have found it to have been obvious to interchange such one compound for the other. Here, the selection of beta-carotene, if indeed less potent than the claimed beta-cryptoxanthin,

would have involved no more than a dosage modification so that the two compounds were exactly interchangeable. The same or similar effect would have been readily expected.

Accordingly, the claims are deemed properly rejected and none of currently in condition for allowance.

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1614

November 21, 2010